

SEP - 7 2001

Premarket Notification (510(k)) Summary

510(k) Number: K011806

Product Name: Protégé™ Self-expanding Nitinol Stent with StarPort™ Delivery Technology (Biliary Indication)

Common Name: biliary stent

Class: Class II, 21 CFR 876.5010

Submitter's Name:	Official Contact:
Sulzer IntraTherapeutics Inc.	Maria Brittle
651 Campus Drive	Sr. Reg/Clin/Training Associate
St. Paul, MN 55112	Telephone: 651-697-2018
	Fax: 651-697-4808

Summary Preparation Date: June 7, 2001

This summary is provided in compliance with section 513(I)(3)(A) of the Act and summarizes the safety and effectiveness information contained in this premarket notification submission for a 6 Fr delivery catheter with added feature. Substantial equivalence is claimed to the 7 Fr Protégé™ Self-expanding Nitinol Stent with StarPort™ Delivery Technology.

The Protégé™ Self-expanding Nitinol Stent with StarPort™ Delivery Technology is intended as a palliative treatment of malignant neoplasms in the biliary tree.

The Protégé™ stent is a self-expanding nitinol (nickel-titanium alloy) stent provided in multiple lengths, (20, 30, 40, 50, 60, 70 and 80 mm) and diameters (6, 7, 8 and 9 mm). The stent is electropolished. The stent is premounted on an 80 or 135 cm working length 6F, 0.018" (or 0.014") over-the-wire delivery catheter designed for transhepatic access. Upon deployment, the stent achieves its predetermined diameter and exerts a constant, gentle outward force to establish patency in the biliary ducts. The disposable StarPort Delivery Technology system is comprised of an inner and outer sheath, which are locked together with a safety lock.

Biocompatibility testing meets FDA's "Guidance for the Content of Premarket Notifications for Metal Expandable Biliary Stents" (2/98). Bench tests of performance characteristics were performed on the 6 Fr system to the same specifications as the 7 Fr system, demonstrating equivalency in performance.

The Protégé™ Self-expanding Nitinol Stent with StarPort™ Delivery Technology, 6 Fr system, is substantially equivalent to the currently marketed Protégé™ Self-expanding Nitinol Stent with StarPort™ Delivery Technology, 7 Fr system, (K003040) in intended use, materials, technological characteristics and performance.



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Maria E. Brittle
Regulatory Affairs Manager
Sulzer IntraTherapeutics, Inc.
651 Campus Drive
ST. PAUL MN 55112

Re: K011806
Protégé™ Self-Expanding Nitinol Stent with StarPort™
Delivery Technology (Biliary Indication), 6 Fr delivery catheter
Regulatory Class: II
21 CFR 876.5010
Product Code: 78 FGE
Dated: June 7, 2001
Received: June 11, 2001

Dear Ms. Brittle:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

The Office of Device Evaluation has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the Warnings section of the device's labeling:

The safety and effectiveness of this device for use in the vascular system have not been established.

Furthermore, the indication for biliary use must be prominently displayed in all labeling, including pouch, box, and carton labels, instructions for use, and other promotional materials, in close proximity to the trade name, of a similar point size, and in bold print.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

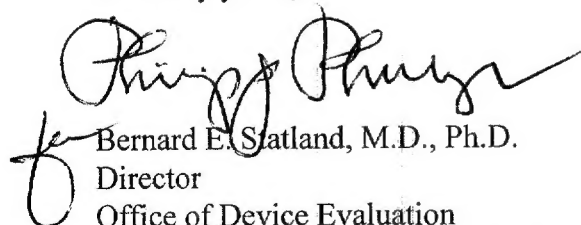
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification if the limitation statement above is added to your labeling, as described.

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

If you desire specific information about the application of other labeling requirements to your device (21 CFR Part 801 and additionally Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4616. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Bernard E. Slatland".

Bernard E. Slatland, M.D., Ph.D.

Director

Office of Device Evaluation

Center for Devices and Radiological Health

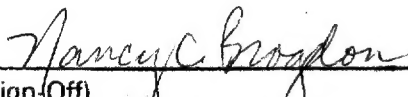
Enclosure

510(k) Number (if known): K011806

Device Name: Protégé™ Self-Expanding Nitinol Stent with StarPort™ Delivery Technology (Biliary Indication), 6 Fr delivery catheter

FDA's Statement of the Indications For Use for device:

The Protégé™ Self-Expanding Nitinol Stent with StarPort™ Delivery Technology (Biliary Indication) is intended as a palliative treatment of malignant neoplasms in the biliary tree.


(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K 011806

Prescription Use ☒ OR Over-The-Counter Use ☐
(Per 21 CFR 801.109)